

CLAIMS

1. A collapsible filter element for a transcatheter embolic protection device,
the filter element comprising:

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a collapsible filter body which is movable between a collapsed
stored position for movement through a vascular system and an
expanded position for extension across a blood vessel such that
blood passing through the blood vessel is delivered through the filter
element;

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a proximal inlet portion of the filter body having one or more inlet
openings sized to allow blood and embolic material enter the filter
body;

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a distal outlet portion of the filter body having a plurality of outlet
openings sized to allow through-passage of blood, but to retain
embolic material within the filter body;

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the distal outlet portion of the filter body in the region of the outlet
openings having means for reducing shear stress on blood passing
through the outlet openings.

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2. A filter element as claimed in claim 1 wherein the shear stress reducing
means includes lead-in radiussed portions of the filter body leading to the
outlet holes.

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3. A filter element as claimed in any preceding claim wherein the shear stress
reducing means includes lead-out radiussed portions of the filter body
leading from the outlet holes.

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4. A filter element as claimed in any preceding claim wherein the outlet holes are generally circular.
- 5 5. A filter element as claimed in any preceding claim wherein the proximal inlet portion of the filter body in the region of the inlet openings has means for reducing shear stress on blood passing through the inlet openings.
- 10 6. A filter element as claimed in claim 5 wherein the shear stress reducing means includes lead-in radiussed portions of the filter body leading to the inlet holes.
- 15 7. A filter element as claimed in claim 5 or 6 wherein the shear stress reducing means includes lead-out radiussed portions of the filter body leading from the inlet holes.
- 20 8. A filter element as claimed in any preceding claim wherein the filter is of a polymeric material.
9. A filter element as claimed in any preceding claim wherein the filter body defines a three dimensional matrix.
- 25 10. A filter element as claimed in any preceding claim wherein the filter body is of a resilient elastomeric material.
11. A filter element as claimed in any preceding claim wherein the filter body is of a polyurethane elastomer.
- 30 12. A filter element as claimed in any preceding claim wherein the filter body is of a polycarbonate urethane material.

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13. A filter element as claimed in any preceding claim wherein the filter body is covered with a hydrophilic coating, the openings being provided in the coating.
- 5 14. A filter element as claimed in any of claims 2 to 13 wherein the filter is of a polymeric material and the raduissed portions are formed by solvent polishing of the polymeric material.
- 10 15. A filter element as claimed in any preceding claim wherein the porosity of the distal portion of the filter body decreases towards the distal end of the filter.
- 15 16. A filter element as claimed in claim 15 wherein the overall porosity of the distal portion of the filter element is from 5% to 40%.
17. A filter element as claimed in claim 14 or 15 wherein the overall porosity of the distal portion of the filter element is form 8% to 21%.
- 20 18. A filter element as claimed in any of claims 15 to 17 wherein the transverse cross sectional areas at longitudinally spaced-apart locations of the distal portion are substantially the same.
- 25 19. A filter element as claimed in any of claims 15 to 18 wherein the distal portion is of generally conical shape having a radial dimension which decreases towards a distal end of the filter element.
- 30 20. A filter element as claimed in any of claims 15 to 19 wherein the distal portion includes a blind section adjacent to the distal end of the filter element.

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21. A filter element as claimed in claim 20 wherein the blind portion extends longitudinally for at least 5% of the length of the distal portion.
- 5 22. A filter element as claimed in claim 20 or 21 wherein the blind portion extends longitudinally for less than 30% of the length of the distal portion.
- 10 23. A filter element as claimed in any of claims 15 to 22 wherein the number of outlet holes increases towards an outer edge of the distal outlet portion of the filter body.
24. A filter element as claimed in any preceding claim wherein there are between 200 and 1000 outlet openings with an average diameter of between 50 and 200 microns.
- 15 25. A filter element as claimed in claim 24 wherein there are between 200 and 300 outlet openings with an average diameter of approximately 150 microns.
- 20 26. A filter element as claimed in claim 24 or 25 wherein there are at least 200 outlet openings with an average diameter of no more than 200 microns.
27. A filter element as claimed in any of claims 24 to 26 wherein there are less than 1000 openings with an average diameter of at least 50 microns.
- 25 28. A filter element as claimed in any preceding claim wherein the openings are sized such that shear stress imparted to blood flowing through the filter body at physiological flow rates is less than 800Pa.

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29. A filter element as claimed in claim 28 wherein the shear stress imparted to blood moving through the filter body at physiological flow rates is less than about 400Pa.
- 5 30. A filter element as claimed in claim 29 wherein the shear stress imported to blood moving through the filter body at physiological flow rates is less than about 200Pa.
- 10 31. A filter element as claimed in any preceding claim wherein the openings are generally circular openings.
32. A filter element as claimed in any preceding claim wherein said filter body, when in a deployed configuration includes a generally cylindrical intermediate section between said proximal and distal portions.
- 15 33. A filter element as claimed in claim 32 wherein the distal section of the filter body is generally tapered when in a deployed configuration.
- 20 34. A filter element as claimed in claim 33 wherein said distal section of said filter body comprises at least a portion of the filter element.
35. A filter element as claimed in any of claims 32 to 34 wherein said intermediate section of said filter body comprises at least a portion of the filter element.
- 25 36. A filter element as claimed in any of claims 32 to 35 wherein the intermediate section of said filter body includes a circumferential groove.
- 30 37. A filter element as claimed in any preceding claim wherein said filter body, when in a deployed configuration is defined by a generally elongated

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shape, having an intermediate section with an axial dimension and a transverse dimension, the ratio of the axial dimension to the transverse dimension being at least 0.5.

- 5 38. A filter element as claimed in claim 37 wherein the ratio of the axial dimension to the transverse dimension is at least 1.0.
- 10 39. A filter element as claimed in any preceding claim wherein the filter body includes a guidewire lumen extending co-axially of a longitudinal axis of the filter body.
40. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:

15 a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element, the filter body having a proximal end, a longitudinal axis and a distal end;

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a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

25 a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

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the porosity of the distal portion of the filter body decreasing towards the distal end of the filter.

- 5 41. A filter element as claimed in claim 40 wherein the overall porosity of the distal portion of the filter element is from 5% to 40%.
42. A filter element as claimed in claim 40 or 41 wherein the overall porosity of the distal portion of the filter element is from 8% to 21%.
- 10 43. A filter element as claimed in any of claims 40 to 43 wherein the transverse cross sectional areas at longitudinally spaced-apart locations of the distal portion are substantially the same.
44. A filter element as claimed in any of claims 40 to 43 wherein the distal portion is of generally conical shape having a radial dimension which decreases towards a distal end of the filter element.
- 15 45. A filter element as claimed in any of claims 40 to 44 wherein the distal portion includes a blind section adjacent to the distal end of the filter element.
- 20 46. A filter element as claimed in claim 45 wherein the blind portion extends longitudinally for at least 5% of the length of the distal portion.
47. A filter element as claimed in claim 45 or 46 wherein the blind portion extends longitudinally for less than 30% of the length of the distal portion.
- 25 48. A filter element as claimed in any of claims 40 to 47 wherein the number of outlet holes increases towards an outer edge of the distal outlet portion of the filter body.
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49. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:

5 a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;

10 a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

15 a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

the filter body comprising a membrane of polymeric material;

20 wherein there are between 200 and 1000 outlet openings with an average diameter of between 50 and 200 microns.

25 50. A filter element as claimed in claim 49 wherein there are between 200 and 300 outlet openings with an average diameter of approximately 150 microns.

51. A filter element as claimed in claim 49 or 50 wherein there are at least 200 outlet openings with an average diameter of no more than 200 microns.

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52. A filter element as claimed in any of claims 1 to 3 wherein there are less than 1000 openings with an average diameter of at least 50 microns.
53. A filter element as claimed in any of claims 49 to 52 wherein the openings are generally circular openings.
54. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:
- 10 a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;
- 15 a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;
- 20 a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;
- the filter body comprising a membrane of polymeric material;
- 25 wherein the openings are sized such that shear stress imparted to blood flowing through the filter body at physiological flow rates is less than 800Pa.

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55. A filter element as claimed in claim 54 wherein the shear stress imparted to blood moving through the filter body at physiological flow rates is less than about 400Pa.
- 5 56. A filter element as claimed in claim 55 wherein the shear stress imparted to blood moving through the filter body at physiological flow rates is less than about 200Pa.
- 10 57. A filter element as claimed in any preceding claim wherein the openings are generally circular openings.
58. A collapsible filter element for a transcatheter embolic protection device, the filter element comprising:
- 15 a collapsible filter body which is movable between a collapsed stored position for movement through a vascular system and an expanded position for extension across a blood vessel such that blood passing through the blood vessel is delivered through the filter element;
- 20 the filter body having a longitudinal axis a proximal inlet portion, a distal outlet portion and an intermediate section extending between the proximal portion and the distal portion;
- 25 a proximal inlet portion of the filter body having one or more inlet openings sized to allow blood and embolic material enter the filter body;

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a distal outlet portion of the filter body having a plurality of outlet openings sized to allow through-passage of blood, but to retain embolic material within the filter body;

5 the filter body having a guidewire lumen co-axial with the longitudinal axis;

10 wherein in a deployed configuration the intermediate section is generally cylindrical with an axial dimension and a transverse dimension, the ratio of the axial dimension to the transverse dimension being at least 0.5.

59. A filter element as claimed in claim 58 wherein the ratio is at least 1.0.

15 60. A transcatheter embolic protection device including:

a delivery system comprising:

20 a tubular member having a longitudinal axis, distal and proximal portions, said distal portion of the tubular member being removably advanceable into the vasculature of a patient;

25 a medical guidewire longitudinally axially movable in said tubular member and having distal and proximal portions;

and a filter element as claimed in any preceding claim, the filter body having;

30 a first collapsed, insertion and withdrawal configuration and a second expanded, deployed configuration;

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5 a proximal inlet section and a distal outlet section, said proximal inlet section including inlet openings which are operable to admit body fluid when the filter body is in the second expanded configuration;

a plurality of outlet openings disposed on at least a portion of the filter element adjacent to the distal outlet section;

10 wherein said filter body is moved between said first and second configurations by displacement of said delivery system.

61. A device of claim 60 wherein the filter body has collapsible filter frame operably coupled thereto.

15 62. A device as claimed in claim 61 wherein said frame comprises a plurality of support arms having proximal and distal ends.

20 63. A device of claim 62 wherein the arms are formed of an elastic shape memory material.

64. A device of any of claims 61 to 63 wherein said frame is constructed such that filter body is biased toward said second, deployed configuration.

25 65. A device of any of claims 62 to 64 wherein said inlet openings are defined at least partially by said arms.

30 66. A device of any of claims 62 to 65 wherein proximal portions of said arms extend generally outwardly and distally from said guidewire when said filter body is in said second, deployed configuration.

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67. A device of any of claims 66 to 65 wherein distal portions of said arms extend generally outwardly and proximally from said guidewire when said filter body is in said second, deployed configuration.
- 5 68. A device of any of claims 60 to 67 wherein the distal portion of the tubular member further includes a pod for receiving therein the filter body when in said first, collapsed configuration.
- 10 69. A device of claim 68 wherein said filter body is urged into said first, collapsed configuration by said pod when the guidewire is moved proximally.
70. A device of any of claims 60 to 69 wherein said guidewire is solid.
- 15 71. A device of any of claims 60 to 70 wherein said filter body comprises a sleeve slidably disposed on said guidewire.
72. A device of claim 71 further comprising stops for limiting the range of longitudinal movement of the sleeve on said guidewire.
- 20 73. A device of claim 72 wherein the sleeve further comprises a guidewire member distal to the filter body tapering distally.